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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,392	11/23/2001	George Jackowski	2132.097	4945

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,392	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment filed on September 22, 2003 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2-38 are cancelled.
2. Claims 39-46 are added to the instant application.

Election/Restrictions

2. In view of the newly added claims, the following restriction is set forth below

I. Claim 1, drawn to biopolymer markers, classified in class 436, subclass 512.

II. Claim 39-43, drawn to a method for diagnosing insulin resistance, classified in class 436, subclass 86.

III. Claim 44-46, drawn to a diagnostic kit, classified in class 422, subclass 119.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products from invention I, can be practiced with another materially different process other than invention II, such as isolation and separation of the specific analytes.

4. Similarly, inventions III and II are also related as product and process of use. Likewise, invention III can be practiced by materially different process other than inventions II, such as isolation and separation.

5. Inventions I and III are patentably distinct and unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention I is directed to biompolymers consisting of specific polypeptides, whereas invention III is directed to polyclonal antibodies produced against the polypeptide markers. Both polypeptides and antibodies are patentably distinct in terms of structure and functions. Therefore, inventions I and III are distinct and unrelated inventions.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for the other, therefore restriction for examination purposes as indicated is proper.

7. Newly submitted claims 39-46 directed to an invention that is independent or distinct from the invention originally claimed for reasons mentioned above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *In re Wands, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*, enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The invention is directed to identify a particular disease, i.e. insulin resistance, by determining the presence of certain biomarkers in the sample, such as SEQ ID NO. 1, 2 or 3. However, the specification does not sufficiently show that the instant recited SEQ ID No. 1-3 can be unequivocally served as the biomarkers for insulin resistance disease. Applicants assert that Figure 1, *"a photograph of a gel which is indicative of the presence/absence of the marker in disease vs. control,..."* (page 46, third paragraph) Applicants further assert that different bands, i.e. proteins now designated as SEQ ID No. 1, 2 or 3 in the instant application, *"related to Insulin Resistance were found."* (supra, second paragraph) and the relative strength, e.g. the up or down regulation of the marker relative to categorization of disease state is deduced. (supra, third paragraph) Nevertheless, the sample size in the instant application does not appear scientifically reliable to indicate that the recited polypeptides, i.e. No. 1-3, are "markers" for insulin resistance. Applicant provides gel electrophoresis from insulin patients versus healthy people. (See Figure 1) The total sample size in this particular experiment is 5, including 2 insulin resistance patients, and 3 healthy people. (See Figure 1, bands 2-3 representing insulin resistance samples, and bands 6-8 representing healthy people samples) Taken

together, the subsequent MS fragmentation and protein sequence analysis is wholly based on the 5 samples, 2 for insulin resistance patients and 3 for healthy people. To be a specific biomarker for a particular disease, the marker must be sufficiently specific to distinguish one disease from the other in order to avoid false positive results. The sample size is too small to be scientifically reliable, and it would certainly impose undue burden of experimentation to one skill in the art to use and make the invention under *In re Wands, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Borden et al. (WO9604790)

Borden et al. teach using various mammalian betaine gamma-aminobutyric acid transporter comprising the recited SEQ ID No. 2 (See SEQ No. 1, residue 583-595) Borden et al. also teach using the markers for screening and diagnosis of GABA associated abnormalities, particularly psychiatric disorder. (Abstract)

12. Claim 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Waterham et al. (Biochem. Biophys. Res. Commu. (1999) 263: 213-218)

Waterham et al. teach cloning human carnitine octanolyltransferase comprising the recited SEQ ID No. 1 (See residue from 187-198).

Response to Applicant's Arguments

Enablement

13. Applicant's arguments on the rejections of 35 U.S.C, §112, first paragraph (enablement) has been considered but the rejection is being maintained.

Applicant argues that the guidance and examples from the instant specification (page 35-47) together with the experimental data (Figure 1 and 2) would enable one ordinary skill in the art to use and make the instant invention. Applicant's argument is considered but appears not persuasive. The examiner has pointed out earlier in this Office Action concerning the sample size of the experimentation. Supra. Applicant admits that there are two insulin resistance and three healthy people participating in the experiment. (See Response Remarks, page 17, second paragraph) The sample size, particularly merely 2 patients for the target of interests, lacks typical representation for the general population. In another word, the instant application does not have scientifically reliable statistical weight in support of the recited "insulin resistance marker." Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Supra.

Rejection under 35 U.S.C. 102 (b)

14. Applicant argues that the recited claim 1 (1) using "consisting of ", therefore limits the metes and bounds of the recited peptides, and (2) detects insulin resistance disease other than ones disclosed in the prior arts. Accordingly, the instant claim 1 is not anticipated by and patentably distinct from the prior arts. Applicant's arguments have been considered but are not persuasive.

First, claim 1 recites "A biopolymer marker peptides selected from the group *consisting of* amino acid .. SEQ ID No. 1....SEQ ID No. 3 diagnostic for insulin resistance." The language "consisting of" refers to Markush group species selection. The recited "consisting of" language merely limits the selection of the peptide species, not the peptide itself. The recited claim 1 can still be read as a polymarker peptide, e.g. SEQ IN No. 1-3, "comprising" its down and upstream residues, thus broadly construing the claim language would be encompassed by the prior art.

Second, applicant argues that the recited polypeptides possessing a patentably different use, i.e. insulin resistance, other than psychiatric monitoring or lipid metabolism disclosed in the prior art. It has been held that a recitation of *the intended use* of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Accordingly, the recited intended use in the instant product claim is not given any patentable weight for examination.

Request for rejoining newly added claims for examination

15. Applicant asserts that the newly added claims 39-46 are directed to a non-elected claims, and requests for rejoinder for reexamination if amended claim 1 is allowable under *Ochiai*

decision. Applicant's request is considered but appears not persuasive because there is no allowable subject matter indicated in this Office Action. Accordingly, newly added claims 39-46 are withdrawn from consideration.

Conclusion

16. No claim is allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
Art Unit 1641

November 18, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/18/03